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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,068	08/26/2000	Ralph Evan McGinnis		6879

7590

10/02/2002

Robert McGinnis
1575 West Kagy Boulevard
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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/623,068	Applicant(s) MCGINNIS ET AL.	
	Examiner KENNETH HORLICK	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Amendment B filed 10/01/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53, 55, 56 and 58-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-20, 22, 33-50, 52 and 78-96 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21, 23, 28-30, 51, 53, 59-77, 97-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> _____ |

1. Due to confusion as to which claims are pending in this application, it has been forwarded to the PCT Legal Office for review. It appears that the amendments which were requested to be entered on August 26, 2000 were not officially entered; thus, the claims pending as of the national stage filing were 1-96 as filed in the Article 34 amendment of May 22, 2000. Should applicant wish to amend the claims as intended in the August 26, 2000 letter, such amendments will have to be filed anew. Accordingly, the status of claims 1-96 as indicated in the previous Office action stands correct.

Maintained Rejections

2. Claims 1, 2, 21, 23, 28-30, 51, 53, and 59-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1 and 2 are confusing because they do not "distinctly claim" any invention. Such claims are clearly not in compliance with U.S. patent practice.

B) Claims 28 and 29 are confusing because they recite a further step "f", but the prior claims already have a step "f". It is unclear if a further step "g" is intended.

C) Apparatus claims 24-27, 31, 32, 55, 56, and 58 are confusing because they do not set forth any searchable apparatus components. These claims are clearly not in proper “means plus function” format, as they merely refer to steps of prior method claims. Thus, it is completely unclear what apparatus is encompassed in the claims, and on what basis a prior art search should be conducted.

D) Claims 59-77 are confusing because they are drawn merely to a “use”. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986).

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, and 59-77 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Neither an “invention” nor “use” is included in the statutory categories of inventions.

New Ground of Rejection Necessitated by the Amendment

4. New claims 97 and 98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These apparatus claims are confusing

because it cannot be determined from the specification what structural components satisfy the recited “means plus function” language. The claims require “means for determining information...” and “means for transforming...information...”. Current practice under 35 U.S.C. 112, sixth paragraph requires that “means plus function” language in claims be limited to the “means” as set forth in the specification. However, the instant specification does not appear to describe even a single specific embodiment of what apparatus components are to be construed as the “means” in the claims. The portions of the specification pointed out in the response, at page 6, merely describe the apparatus in terms of functional definition, rather than exemplify an actual apparatus and its structural elements. The general description of “oligonucleotide technology” and “mass spectrometry” in the specification does not remedy this problem, as this does not set forth any structural components of an apparatus. In fact, the use of these terms in claim 98 renders it further confusing.

Should applicant wish to pursue apparatus claims in future prosecution (this is NOT an invitation to prosecute after final rejection), the following guidance is provided. If a specification describes an apparatus comprising an agarose gel for separating nucleic acids, for example, then in an apparatus claim comprising a “means for separating nucleic acids”, it is clear what such a means is and what must be searched for in the prior art. That is, the agarose gel is a concrete example of the recited “means”, and the claims are to be limited to it, and any other concrete examples the specification might provide. But lacking any such concrete examples in the specification, “means plus function” language cannot be interpreted or searched.

Claim status summary and allowable subject matter

5. Claims 3-20, 22, 33-50, 52, and 78-96 are allowable. Claims 1, 2, 21, 23-32, 51, 53, 55, 56, 58-77, 97, and 98 are free of the prior art, but are rejected for other reasons. The closest prior art is Kruglyak (1997) which is discussed on page 4 of the specification, and teaches the use of a genetic map of biallelic markers in linkage studies. No prior art has been found teaching or suggesting a set of oligonucleotides complementary to a group of two or more bi-allelic covering markers of the same species, said group systematically covering a CL-F region, the CL-F region being a collection of points on a two-dimensional plane, the two-dimensional plane having the two orthogonal dimensions of chromosomal location and least common allele frequency; nor methods involving detection or determination of such a group of markers.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

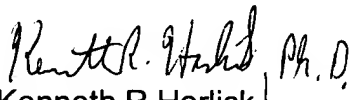
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

September 24, 2002